Medtronic

Aquamantys® System Generator Verification

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Intended Use of this Document

WARNING: The information contained in this document is intended for the use of qualified personnel only. Biomedical technicians (e.g., ICC Certified Biomedical Equipment Technician [BMET]) or similar personnel performing the steps outlined here shall be fully familiar with all documentation on the functions, operations, warnings and components of the Aquamantys® System. Serious injury can result if the activities described in this document are attempted by unqualified persons and if warnings identified in the text are neglected.

Note: The information contained in this document was accurate at the time of publication. Medtronic reserves the right to make changes to the product described in this manual without notice and without incorporating those changes into any products already sold.

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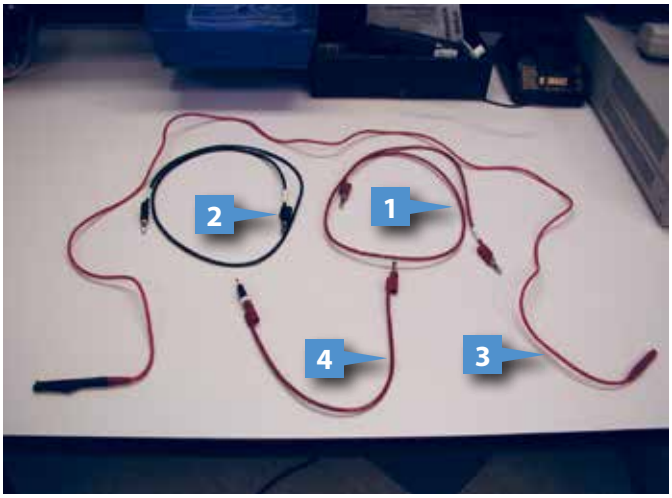
Test Leads Required



1. (1) Long red lead with (2) 4mm ends
2. (1) Long black lead with (2) 4mm ends
3. (1) Long lead with (1) 4mm end and (1) banana clip
4. (1) Short red lead with (1) 4mm end and (1) 2mm end

Aquamantys® Generator Adjustments

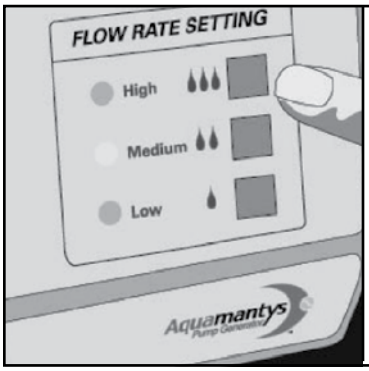
Power on Aquamantys generator, adjust power up and down

Adjusting the RF Power Setting

Press the △ button to increase the RF power and press the ▽ button to decrease the RF power (Figure 10-2).

The RF power setting changes in increments of 5 watts in the range of 20 to 100 watts, and in increments of 10 watts in the range of 100 to 200 watts. Release the button when the desired RF power setting is displayed. An alarm tone will sound when the power reaches 200 watts and when it is lowered to 20 watts. The RF power setting cannot be adjusted while the unit is being activated.

Adjust flow settings



Adjusting Flow Rate Setting

The saline flow rate setting is adjusted by pressing the button next to the desired flow rate (Figure 10-4). Flow rate options include:

- High saline flow rate **High**
- Medium saline flow rate **Medium**
- Low saline flow rate **Low**

The Flow Rate Setting Indicator next to the selected flow rate will be illuminated amber to indicate the current flow rate setting. If a flow rate setting is not manually selected, the medium setting is selected as the default setting. The saline flow rate setting cannot be adjusted while the unit is being activated.

RF Activation

When 2mm connector #1 is shorted to 4mm connector #1, the Aquamantys® bipolar RF output will be active from 4mm connector #1 to 4mm connector #2

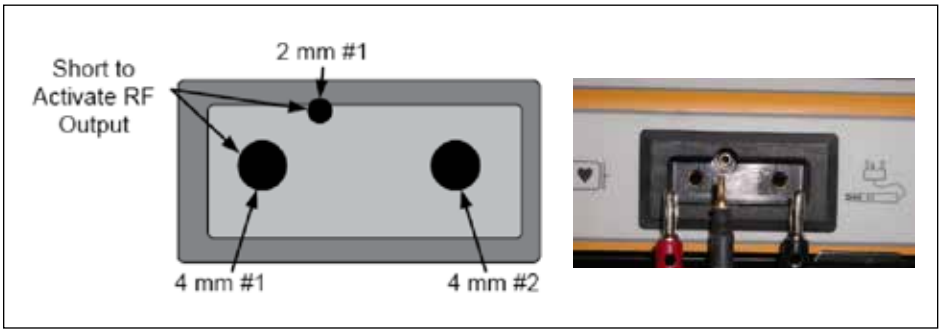
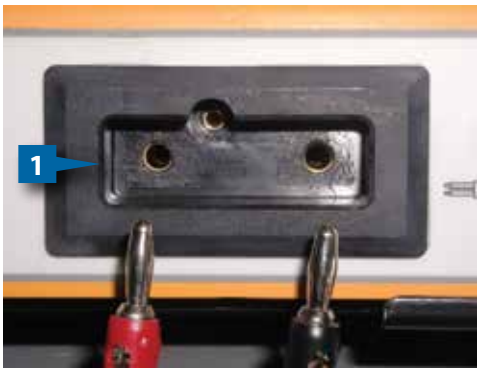
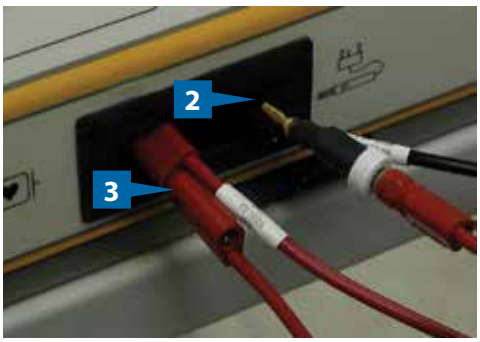


Figure 1 Aquamantys bipolar output socket; RF output activation



1 Insert red (active) and black 4mm test lead ends into bipolar socket



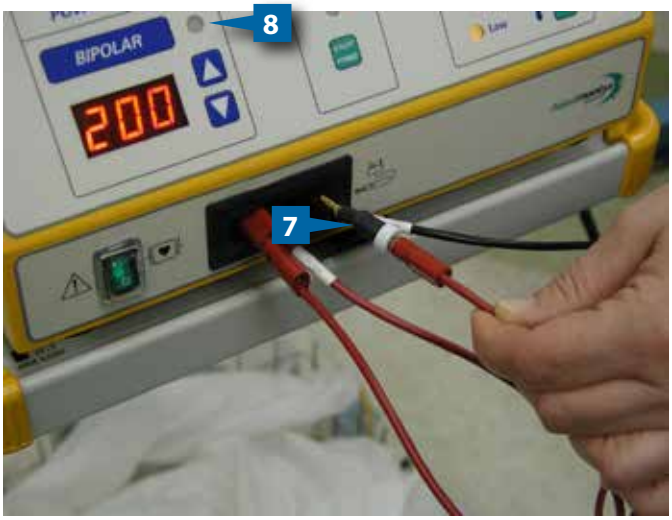
2 2mm pin will activate RF when inserted into center hole of bipolar socket

3 Insert short red 4mm end of test lead into long red lead

4 To activate RF output, insert 2mm pin of short red lead into 2mm center hole of bipolar socket

5 Blue bipolar active LED will light up and stay lit while RF is activated

6 **WARNING:** metal of loose ends of test cables become extremely hot and will cause burn injury if contact with skin is made while RF is active



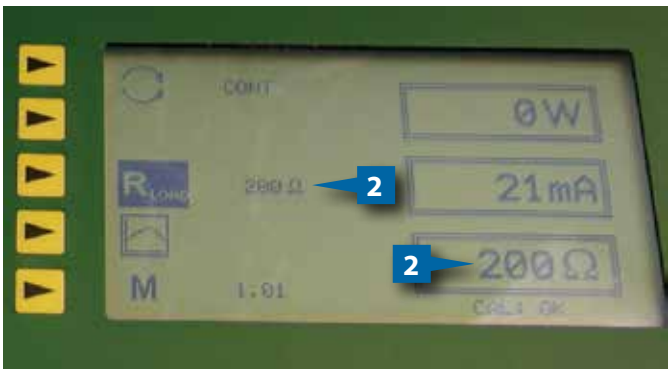
7 To deactivate RF output, remove 2mm pin from bipolar socket

8 Bipolar active LED will go off

RF Leakage Current*

***WARNING:** Use extreme caution during this test. Metal ends of test leads are hot during RF activation and will cause burning if in contact with skin!*

1 Power on Aquamantys® generator, adjust power to **200W**, and flow rate to high



2 Power on electro-surgical safety analyzer (power meter) and adjust resistance to **200Ω**

3 Insert opposite end of black test lead into inactive port of power meter

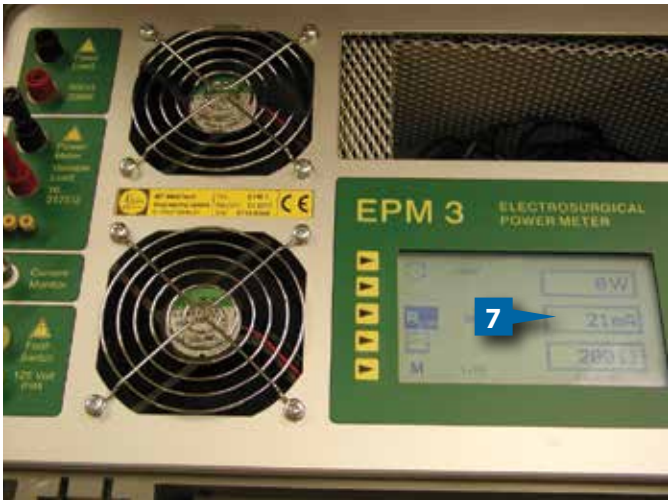
Do not attach red test lead from bipolar socket to power meter at this time

*Electrosurgical power meter shown in this section is for illustrative purposes only. Customer test equipment may differ.

4 Connect **3rd test lead** with alligator clip end to the earth ground stud on the back of the Aquamantys® generator

5 Insert opposite end of **3rd test lead** into active port of power meter

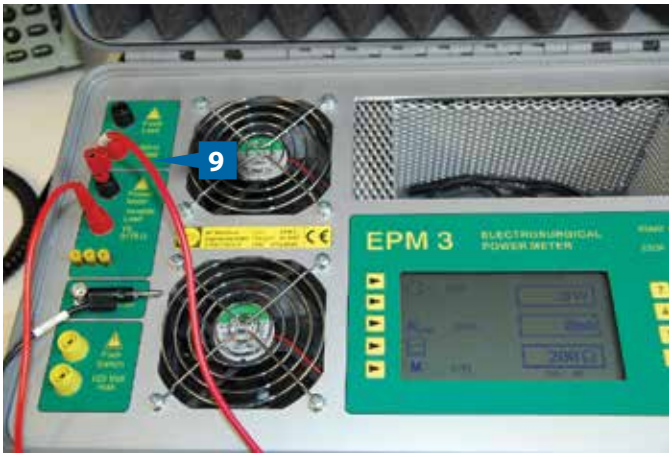
6 Activate RF output



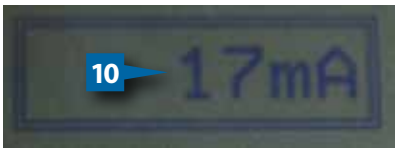
7 Read current measurement on power meter display

*This reading must be below **100mA***

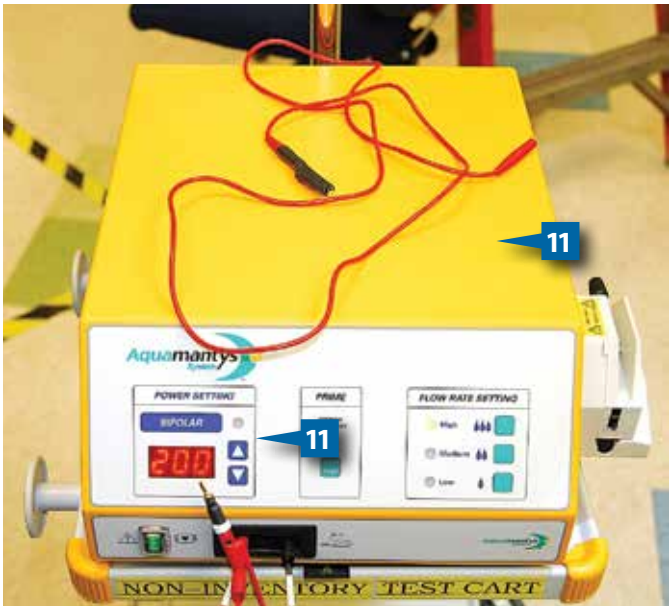
8 Remove black test lead from inactive port of power meter



9 Insert opposite end of red test lead connected to active side of bipolar socket into the inactive port of the power meter, read current measurement on power meter display

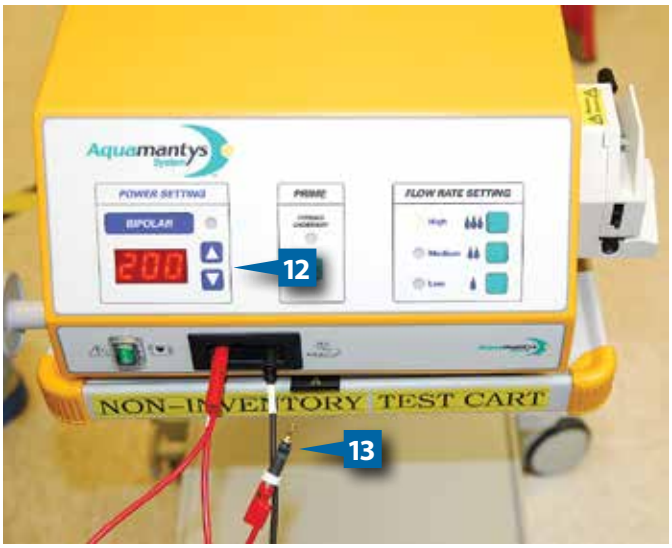


10 *This reading must be below **100mA***



11 Deactivate RF output and remove 3rd test lead from power meter and Aquamantys® generator earth ground stud

RF Output Power:



12 Set power of the Aquamantys generator to **200W**

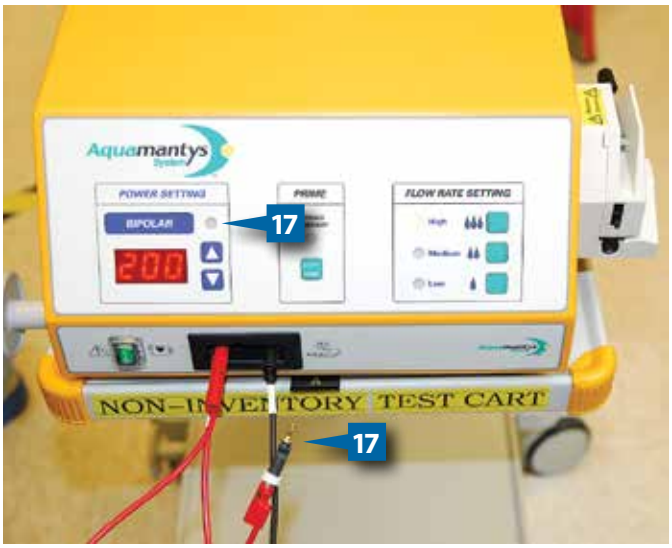
13 Make sure RF output is not active at this point

14 Insert red test lead into active port of power meter and black test lead into inactive port

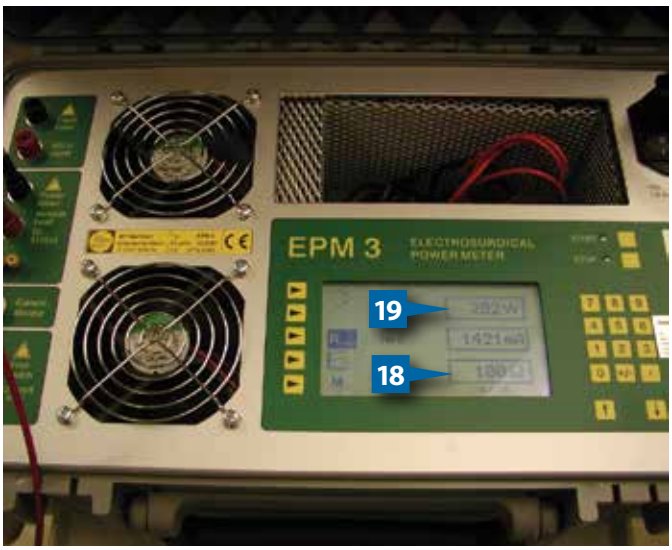
15 Adjust resistance on the power meter to **50Ω**

16 Activate RF power and read measurement on power meter display

*Measurement should be **200W +/- 10%***

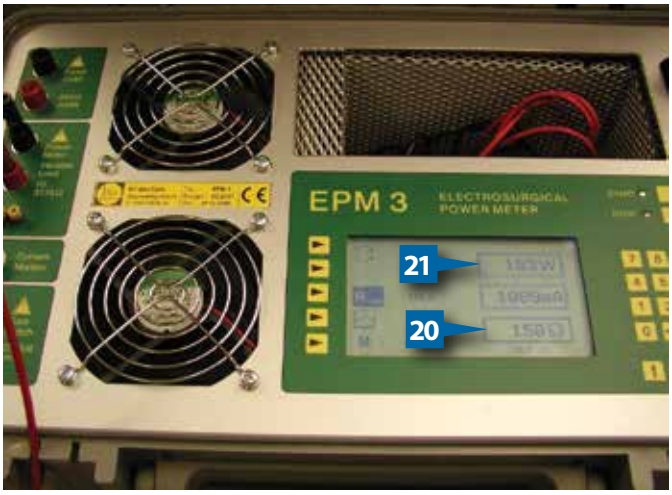


17 Deactivate RF power after each measurement; power can only be adjusted when RF is inactive



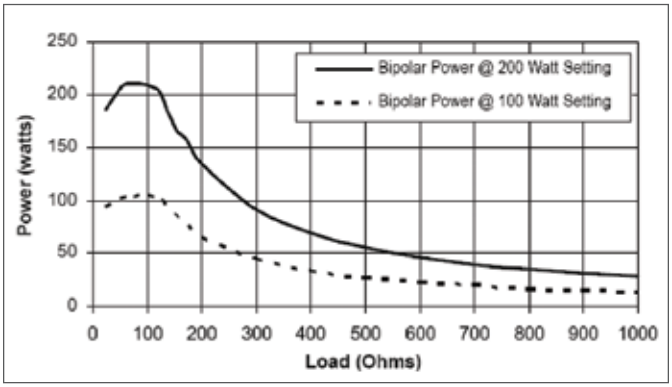
18 Repeat measurement with **100Ω resistance**

19 *Measurement should be **200W +/- 10%***



20 Repeat measurement with **150Ω resistance**

21 *Measurement should be lower than previous readings at lower resistance (see power curve below)*

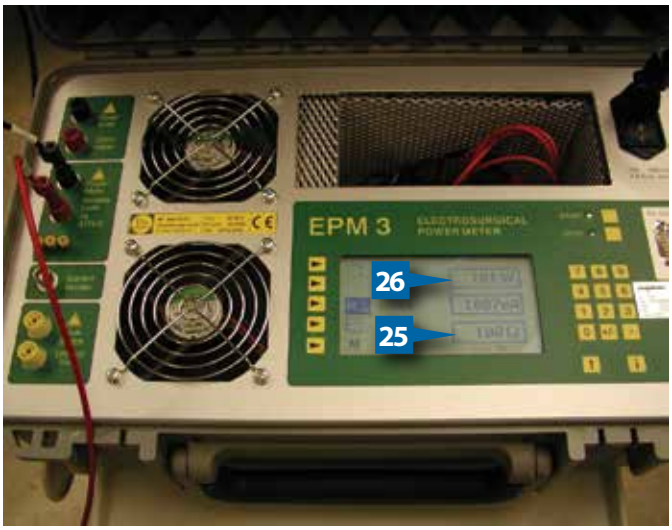


Output Power versus Resistance

22 Adjust power setting on the Aquamantys® generator to **100W**

23 Take measurements at **50Ω**

24 *Measurement should be **100W +/- 10%***



25 Take measurement at **100Ω**

26 *Measurement should be **100W +/- 10%***

27 Take measurement at **150Ω**

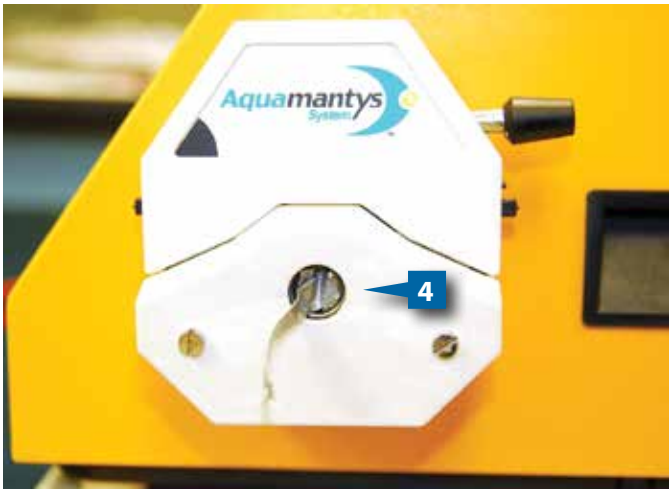
28 *Measurement should be lower than previous readings at lower resistance (refer back to power curve above)*

Pump Head Rotation to Verify Flow Rate Accuracy

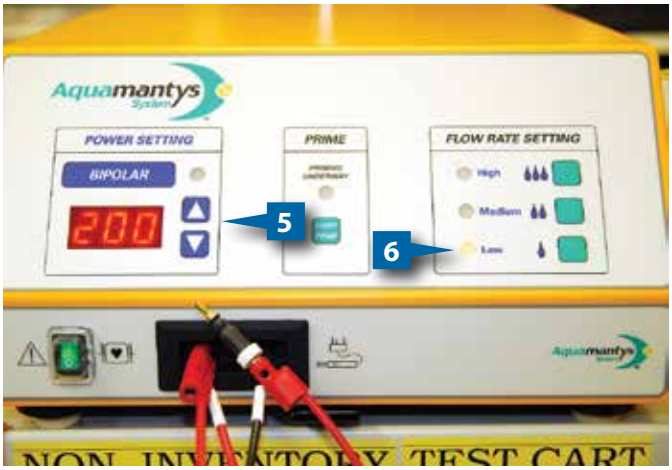
1 Close pump head by moving and locking the pump head lever down toward the rear of the pump generator

2 Remove grommet from pump head

3 Mark a visual reference point



4 Or use a piece of tape and stick to pump shaft



5 Set the Aquamantys® generator power to **200W**

6 Adjust flow rate to **Low**

7 Activate RF output

8 Using a stopwatch as a timer, count number of complete revolutions of pump shaft in **15 seconds**

*Minimum revolutions = **17***
*Maximum revolutions = **23***

Deactivate RF output between measurements

9 **0:15**$_{00}$

10 Count pump shaft revolutions in **15 seconds** at **Medium** flow rate

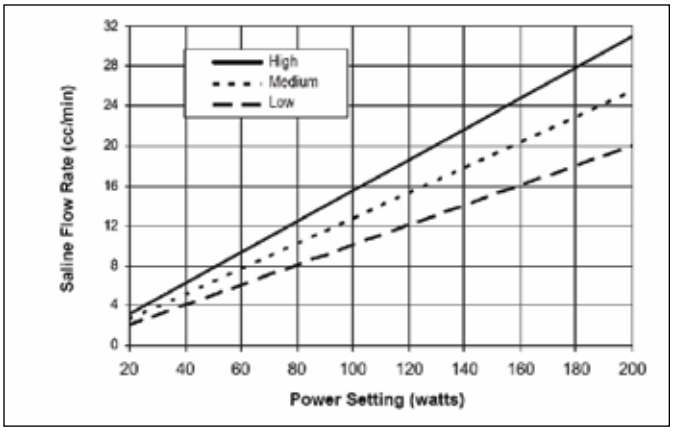
Minimum revolutions = ***22***
Maximum revolutions = ***30***

11 Count pump shaft revolutions in **15 seconds** at **High** flow rate

Minimum revolutions = ***27***
Maximum revolutions = ***36***

12 Count pump shaft revolutions in **15 seconds** at **Prime** rate

Minimum revolutions = ***31***
Maximum revolutions = ***42***



Saline Flow Rate versus Power Setting

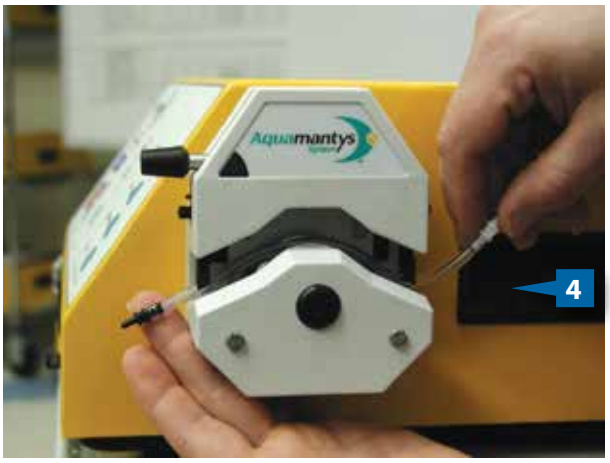
13 Replace grommet

Load Pump Tubing Segment into Pump

1 Open pump head by moving pump head lever toward front of the Aquamantys® generator

2 With black tubing insert facing toward front of Aquamantys generator and white tubing insert facing toward back of Aquamantys generator, insert tubing segment into pump head

3 Black corner of pump head label points to direction of black tubing barp, white corner of pump head label points to direction of white tubing barp



4 Line tubing up inside of guide pins in front and back and hold in place while closing pump head

Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician.
For a listing of indications, contraindications, precautions, and warnings, please refer to the Instructions For Use (IFU) that accompany Aquamantys3 disposable devices and/or the Aquamantys3 System User Guide.

For further information, please call 866-777-9400 or 603-742-1515.
You may also consult our website:
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Lebanon 961-1-370-670
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Poland 48-22-4656900
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70-10-1399 8.12 Rev A